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PHARMACEUTICAL PRODUCTS, MEDICAL DEVICES & FOOD SUPPLEMENTS

REGULATORY PROCESS FOR IMPORTING, REGISTERING, AND DISTRIBUTING IN MEXICO

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These Guidelines are based on 30 years of experience in this field. They provide general information and selected comments on legal issues of interest to our Clients. The following contents are not a comprehensive treatment of the subject matter covered and is not intended to provide specific legal or tax advice. Readers should seek legal advice before taking any action with respect to the matters discussed herein

I. PHARMACEUTICAL PRODUCTS, MEDICAL DEVICES & FOOD SUPPLEMENTS

A. REGULATORY PROCESS FOR IMPORTING, REGISTERING, AND DISTRIBUTING

These guidelines compile current information and experience on registration, and importing into Mexico, or local manufacturing:

- (i) Pharmaceutical Products,
- (ii) Medical Devices, and
- (iii) Food Supplements,

These Guidelines are for general information only, and do not constitute specific legal advice.

The information herein may change since the applicable legislation may also change.

Once the decision to invest, or ship the products to Mexico is taken, we recommend that the foreign company verifies with their Mexican counsel the current legal requirements.

In terms timing and processes, it takes less for the Food Supplements, followed by the Medical Devices and, finally, by the Pharmaceutical Products.

B. INCORPORATION OF A SUBSIDIARY

International companies, depending upon their business plans, can simultaneously incorporate a subsidiary in Mexico for the distribution of its (i) Pharmaceutical Products, (ii) Medical Devices, (iii) Food Supplements, or use a local Mexican distributor.

In our experience, it is recommendable to incorporate a subsidiary in Mexico to have control on the filings, imports, and the distribution in the Mexican market.

C. COFEPRIS (Agency of the Health Ministry)

The filings to obtain the Certificates and Sanitary Registrations will have to be made before the Federal Commission for the Protection Against Sanitary Risks, known as: "**COFEPRIS**", which is an Agency of the Health Ministry.

COFEPRIS's mandate covers:

- i)** Applying the Policy on National Health Risk Protection;
- ii)** Regulate, control and improve: (i) sanitary surveillance, and (ii) evaluation of health risks deriving from products, activities and establishments;
- iii)** Implement the Ministry of Health's attributions on environmental impact on: (i) health in general, (ii) occupational health, (iii) hazardous residues, (iv) sanitation, (v) accidents involving toxic, dangerous or radioactive substances, and (vi) health protection in advertising.

COFEPRIS comprises the following 5 interrelated **General Directorates**:

- i) Medicines and Health Technologies,
- ii) Sanitary Control of Products and Services,
- iii) Environmental Health,
- iv) Sanitary Control on Advertising, and
- v) The National Public Health Laboratory.

D. COFEPRIS - INTERNATIONAL:

COFEPRIS participates at international organizations, associations and forums, with the purpose of exchanging information and increase the protection against sanitary risks.

COFEPRIS is also part of the denominated Trilateral Cooperation, where, together with the United States through the Food and Drug Administration, and Canada, through the Department of Health, the three Parties collaborate and exchange information on pharmaceutical and biological products, medical devices, food and nutritional safety, with the purpose of protecting and promoting human health.

1. PHARMACEUTICAL PRODUCTS

Both: (i) pharmaceutical products manufactured abroad, or (ii) pharmaceutical products manufactured in Mexico but with raw materials totally or partially from abroad, that will be distributed in Mexico, need to be **previously registered** in Mexico by obtaining a "**Sanitary Registry**."

Only a **Mexican company** can file for and be responsible for such registration.

Such Mexican Company will also be registered as a **Health Representative** for such of such pharmaceutical products before COFEPRIS.

The Sanitary Registry of a pharmaceutical product can be transferred later to another Mexican company, including a subsidiary of foreign manufacturing company incorporated in Mexico.

A. SANITARY REGISTRY

After having filed for the Notice of Operation or the Sanitary License, as described below, the next step will be to obtain a **Sanitary Registry** of the pharmaceutical product.

The Health Representative is the one who files and applies for such Sanitary Registry.

COFEPRIS will resolve on this Sanitary Registry Application in around one year.

This Sanitary Registry has a validity of 5 years, with the possibility to be renewed and/or modified by the Health Representative.

COFEPRIS maintains direct a relationship with the Mexican Institute of Industrial Property (IMPI), to make sure that no Sanitary Registry is attempted on a pharmaceutical product, when another is already registered and protected with a current patent in Mexico or abroad (patent linkage).

The **previous step** for obtaining a Sanitary Registry is for the Health Representative to file for either a:

- a. Notice of Operation**, for products manufactured abroad; or a
- b. Sanitary License**, for products manufactured in Mexico with foreign raw materials

a. NOTICE OF OPERATION

For product manufactured abroad.

This Notice applies to pharmaceutical products manufactured abroad to be distributed in Mexico.

To obtain this Notice of Operation the Health Representative has to be previously registered as the Importer of Record of the Product on behalf of foreign manufacturer.

COFEPRIS must verify and certify that the manufacturing process of the Pharmaceutical Product done by the foreign manufacturer complies with all the current requirements established by COFEPRIS and the Health Ministry.

For such certification COFEPRIS will ask from the foreign manufacturer for either a:

i) CERTIFICATE OF GOOD MANUFACTURING PRACTICES

This Certificate is given if the manufacturing company is listed within the Agreements that COFEPRIS has entered into with other Countries. This list is kept and updated by COFEPRIS and is not published. It needs to be consulted on a case by case basis; or

ii) COMPLIANCE CERTIFICATE - MANUFACTURING SITE VISIT ABROAD

If the foreign manufacturer is not part of the foregoing COFEPRIS' List, COFEPRIS Officers will visit the Manufacturing Site of the foreign manufacturer, to determine if it complies with all the requirements and obligations of the Mexican Official Standards for Manufacturing Sites.

This visit has a cost for traveling and lodging, established by COFEPRIS, and it will be performed within 3 to 6 months after the filing request was made.

Once COFEPRIS certifies that the Manufacturing Site abroad complies with all the requirements and obligations of the Mexican Official Standards, it will grant a Certificate of Compliance.

Thereafter the foreign manufacturing company can apply for a Certificate of Good Manufacturing Practices.

The Certificate of Good Manufacturing Practices is issued by COFEPRIS within 10

working days from application.

BOTH CERTIFICATES (Compliance and Manufacturing Practices) are essential in order to obtain the **Sanitary Registry** of the Pharmaceutical product; **or**

b. SANITARY LICENSE

For product manufactured in Mexico with foreign raw materials.

This License applies in case of pharmaceutical products that will be manufactured in Mexico with raw materials totally or partially from abroad.

Similarly, a Health Representative is registered as the importer of the raw materials, for and on behalf of the foreign company supplier.

B. SANITARY REQUIREMENTS FOR PHARMACEUTICAL PRODUCTS - NOMS:

The Health Ministry has issued several Mexican Official Standards ("NOMs"), detailing specific sanitary requirements for certain pharmaceutical products to be allowed to be distributed for human consumption.

The NOM's indicate specific details on the physicochemical and microbiological characteristics that pharmaceutical products must comply, setting the limits and tolerances that required documentation must report.

C. IMPORTER'S LICENSE

Simultaneously the Health Representative should obtain an Importer's License, which should be filed before the Mexican Tax Administration ("SAT").

D. SANITARY IMPORT PERMIT

Thereafter the Health Representative should apply for the corresponding Sanitary Import Permit before COFEPRIS.

COFEPRIS will grant each Import Permit within a term of 40 working days.

After importing the pharmaceutical product, the sale and distribution could be made by any third party (agent or distributor) as convenient.

E. LABELING OF PHARMACEUTICAL PRODUCTS

Mexican labeling legislation, through Mexican Official Standards ("NOM's"), specifies the information expected to appear in Pharmaceutical Product.

Among others, the NOMS require that such information be in Spanish, legible, and understandable.

The label must also show the generic and specific names of the pharmaceutical product, country of origin (as applicable), Sanitary Registry number, expiration date, serial or lot number, and contents.

If a pharmaceutical product is manufactured by a third party the label must include the name of the third party manufacturer. Symbols in the labels are also regulated.

2. MEDICAL DEVICES

Mexico has become an attractive market to medical (health) device manufacturers worldwide. There has been a substantial increase of imports of medical devices into the Mexico in the last years.

The regulatory framework is the General Health Law (the "Health Law"), and the Regulations on Health Devices.

For some time now there have been delays in the reviews of medical device submissions in Mexico due to the high volume of submissions and shortage of staff reviewing such submissions.

Recent legal amendments will help speeding the regulatory process.

The amendment sets out strict rules on deadlines for reviewing submissions for imported devices. It also allows the applicant to know at any time the status of a medical device submission.

A. DEFINITION AND CLASSIFICATION

There is no formal definition in the legislation on what are Medical (Health) Devices.

However, considering the different descriptions in the Health Law, and the COFEPRIS Guidelines for registering medical devices, a definition can be:

Any substance, or mixture of substances, or material, apparatus or instrument, including its applicable software for its use or application, either used alone or in combination, for the: diagnosis, monitoring, or prevention, or process of an illnesses, or disability in humans; as well as those devices employed in the replacement, correction, restoration or modification of the human anatomy, or used for human physiological process.

B. HEALTH AUTHORIZATION AND SANITARY REGISTRY

The Health Law defines which Medical Devices require **Health Authorization** and **Sanitary Registry**.

The Law describes 7 categories of Medical Devices which require Sanitary Registry if they are to be produced, sold or distributed in Mexico:

1. Medical equipment;
2. Prosthesis,
3. Orthosis and Functional Aids;
4. Diagnostic Agents;
5. Odontological Supplies;
6. Surgical Materials and Wound Care; and
7. Sanitary Products.

C. CLASSES (I, II, III):

Under the Regulations on Health Devices, the Medical Devices are divided into **3 Classes** according to their risk level when used in human beings:

a. CLASS I

Are known in the medical practice to have a proven safety and effectiveness, and are generally not introduced into the human body;

b. CLASS II

Are known in the medical practice to have variations in their materials or in their concentrations, and are generally introduced into the human body for less than 30 days; and

c. CLASS III

Are new or recently accepted in the medical practice, or are introduced into the human body permanently or for longer than 30 days.

If the manufacturer has questions on the Classification, those questions should be submitted simultaneously to COFEPRIS and a Mexican customs broker.

Customs brokers keep customs code classification books where they can determine if a permit or registration is required for importation.

D. NOTICE OF OPERATION

This Notice applies to any Medical Device to be distributed in Mexico, either manufactured in Mexico or abroad.

The Distributor applies for this Notice of Operation. If the Medical Devices is imported, the Distributor has to be registered as the Importer of Record of such Medical Device on behalf of the foreign manufacturer.

Through the Notice of Operation the Medical Device will be registered and classified within the Classification maintained by COFEPRIS under the Regulations.

E. MEDICAL DEVICES MANUFACTURED ABROAD

For importing Medical Devices manufactured abroad Mexico the following additional information is required:

- A **Free Sale Certificate**, or equivalent, issued by the health authority of the country of origin, responsible for ensuring that such device complies with local legal requirements of such country of origin, and that it can be used or consumed freely, with no restrictions, in the country of origin. Such certificate should be valid for one year;
- A **Certificate of Manufacturing** from the manufacturer, indicating that the manufacturing was made according to the accepted procedures of the manufacturer's country of origin;

- A **Good Manufacturing Practices Certificate** of the device, issued by the health authority of the country of origin, or the equivalent medical device quality system certification (ISO 13485:2003 certificate); and
- A copy of the **Certificate of Analysis** issued by the manufacturing company, signed by its quality control representative.

F. MEDICAL DEVICE REGISTRATION STEPS

The basic documentary information to include in the Medical Device Registration Filing is:

- Scientific and technical information substantiating that the device complies with safety and effectiveness characteristics;
- The label in Spanish according to corresponding NOM's. See below;
- Additional references to corresponding Sanitary NOM's. See below;
- The instructions for use in Spanish;
- The general description of its manufacturing process;
- A description of its structure, materials, parts, and functions;
- The laboratory tests verifying the specifications of the medical device; and
- Biographical references.

G. SANITARY REQUIREMENTS FOR MEDICAL DEVICES – NOM's

The Health Ministry has issued several Mexican Official Standards ("NOM's") detailing specific sanitary requirements that certain medical devices must comply in order to be allowed to be distributed for human consumption.

The NOM's indicate specific details that medical devices must comply, setting the limits and tolerances that required documentation must report.

H. RESOLUTION TIMING

The time for resolving the registration of a medical device can decrease from 1 year up to 30 days if the Medical Device fulfils with the requirements of either the:

- "Food and Drug Act", and the "Medical Devices Regulations" of Canada, or
- The "Federal Food, Drug and Cosmetic Act" and the "Code of Federal Regulations" of the United States, both under the Agreement that Mexico entered into with these Countries, published in 2010.

Currently the **European Union** is advancing in negotiations with COFEPRIS so that the medical devices originating from countries of the European Union will be granted the same short term approval that the medical devices originating from Canada and the United States receive.

I. VALIDITY TERM

The Medical Device Registry has a validity of **5 Years**, and can be renewed and/or modified through the request of the local Health Representative.

J. IMPORTER'S LICENSE

The Mexican Company acting as the Distributor of Medical Devices has to previously obtain its own Importer's License from the Mexican Tax Authorities ("SAT").

Thereafter the Distributor should apply for the corresponding **Sanitary Import Permit** before COFEPRIS.

The Import Permit will have a validity of 180 calendar days, extendable.

K. LABELING OF MEDICAL DEVICE

The NOM's specify the information expected to appear in medical device labels. Among others, such information must be in Spanish, legible and understandable.

The label must show the generic and specific names of the device, country of origin, Sanitary Registry number, expiration date, serial or lot number, and content materials, as applicable.

The label must include the Sanitary Registration Holder, and name of the Manufacturer, as the case may be. Symbols in the labels are also regulated.

3. FOOD SUPPLEMENTS

A. ADDITIONAL COMPOUNDS ASIDE FROM VITAMINS AND MINERALS.

Under the Health Law, the food supplements must contain additional compounds aside from vitamins and minerals.

If the supplement only contains vitamins and minerals, it will not be called food supplement but "Vitamin Medication". In this case the Vitamin Medication will be subject to the legislation of pharmaceutical products above mentioned.

B. SANITARY IMPORT PERMIT, OR SANITARY IMPORT NOTIFICATION

On September, 2007, in coordination with the Ministry for the Economy, the Health Ministry published the "Agreement that Establishes the Classification of Products whose Import or Export is Subject to Sanitary Regulations from the Ministry of Health".

This Agreement lists the tariff codes of products subject to Health Ministry regulation and specifies which products require either a:

- "Sanitary Import Permit" or
- "Sanitary Import Notification", which must be included in the import documentation submitted by the customs broker.

C. IMPORT APPLICATIONS

There are no specific guidelines for drafting and presenting these documents. COFEPRIS constantly changes the application requirements. It is best to request advice from local counsel with experience in this area.

Once filed, COFEPRIS will indicate which information/documentation additional will be necessary and which it was not.

Currently the documentation to be presented on the food supplements is the following, and depending upon the specific components, as the case may be:

a. PHYSICOCHEMICAL ANALYSIS

Determination of the representative values of the products or supplies to be imported, carried out in the country of origin by the producer or a domestic or foreign laboratory accredited by the corresponding government agency or office, printed on official paper, with the name, signature and position of the Health Representative of the country of origin.

The Health Representative could be a lab supervisor, quality control manager, chemical engineer or any related position.

The validity of such analysis should be specified by lot number.

b. MICROBIOLOGICAL ANALYSIS

Determination of pathogen and non-pathogen microorganisms, carried out in the country of origin by the related government agency or office, printed on official stationery, with the name, signature and position of the Health Representative of the country of origin.

The validity of such analysis should be specified by lot. Most of the times, the microbiological analysis information is described in the products according with the corresponding Mexican Official Norm (NOM);

c. SPECIFIC ANALYSIS

This analysis is carried out in the country of origin by the producer or a domestic or foreign laboratory accredited by the related government agency, printed in official paper.

Specific analyses are requested when products originate from highly polluted regions, radioactive contaminated areas or regions affected by particular diseases such as cholera.

Currently, no specific analyses are required for products from the United States.

- Original labels of the food supplements abroad,
- Label under which it will be distributed in Mexico, and
- As the case may be the following documentation:

i) HEALTH CERTIFICATE

Document issued by the country of origin's health authority which declares that the product complies with sanitary regulations.

It should be valid for one year.

ii) HEALTH DECLARATION

Document issued by the country of origin's health authority, responsible for regulating the process and quality of the products or supplies to be imported, where evidence is provided to guarantee that the product is safe for human use/consumption, indicating its physicochemical composition and including microbiological and specific analysis, when applicable.

The Declaration should also state the geographical origin of the supplement, and the validity of such analysis should be specified by lot number.

iii) FREE SALE CERTIFICATE

For sanitary purposes, the Free Sale Certificate will be a document issued by the foreign health authority responsible for ensuring that the supplement and its inputs comply with all legal requirements and can be used or consumed freely, with no restrictions, in the country of origin.

Such certificate should be valid for one year.

D. IMPORT – CONTENTS OF FOOD SUPPLEMENT

The next step is the specific determination by the Manufacturer and Customs Broker of the contents Food Supplement.

The Mexican importer with its customs broker, are responsible for submitting all needed documentation to the Mexican authorities.

Foreign exporters may be asked to provide additional information to comply with Mexican import provisions. Such information may include labels, certificates of origin, and microbiological analysis. Each case could require different complementary information.

E. NOTICE OF OPERATION

This Notice of Operation should be obtained by the Distributor established in Mexico when importing food supplements that are manufactured abroad and are distributed in Mexico.

The Mexican company that will be acting as the Distributor has to previously obtain its own Importer's License from the Mexican Tax Authorities ("SAT").

F. SANITARY IMPORT PERMIT

Thereafter the Distributor should apply for the Sanitary Import Permit before COFEPRIS of the corresponding Food Supplement.

The Import Permit will have effects for 1 month, extendable.

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Such Permit will be granted by "Specific Number of Food Supplements" or by "Lot of Food Supplements" covering the import permit.

The Import Permit can be obtained in 5 business days.

G. SANITARY REQUIREMENTS FOR FOOD SUPPLEMENTS – NOM's

The Health Ministry has issued several Mexican Official Standards ("NOM's") detailing specific sanitary requirements that certain food supplements must comply in order to be allowed to be distributed for human consumption.

The NOM's indicate specific details that food supplements must comply, setting the limits and tolerances that required documentation must report.

H. LABELING OF FOOD SUPPLEMENTS

The NOM's specify the information expected to appear in food supplements labels. Among others, such information must be in Spanish, legible and understandable.

The label must show the generic and specific names of the food supplements, country of origin, expiration date, serial or lot number, and contents, as applicable.

* * *

We hope you find this information useful for your operations in Mexico.

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Respectfully

Diego Ferrer G.-T. and Jorge Santistevan

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